K013806
1 OF 3

FEB 0 8 2002

3. Summary of Safety and Effectiveness Information

Sponsor	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact	Matthew M. Hull (610) 647-9700 ext. 7191
Name of the Device	Synthes Metallic Spiked Washers
Device Classification(s)	Class II, §888.3030 – Washer, bolt, nut, non-spinal
Substantial Equivalence	Documentation was provided which demonstrated the Synthes Metallic Spiked Washers to be substantially equivalent to other legally marketed devices.
Device Description	The Synthes Metallic Spiked Washers are washers of various sizes with metal spikes arrayed around a center hole.
Indications	The Synthes Metallic Spiked Washers are indicated for ligament reattachment or fixation.
Materials	Stainless Steel and Titanium

K013806
2 of 3

4. Device Name

Proprietary Name: Synthes Metallic Spiked Washers
Common Name: Spiked Washers
Classification Name: Washer, Bolt, Nut, Non-spinal

5. Manufacturer Identification

The devices subject to this Premarket Notification will be manufactured by Synthes (USA), 1101 Synthes Ave., Monument, Colorado 80132 (FDA Registration #1719045).

6. Classification Information

The classification of the Synthes Metallic Spiked Washers are Class II, as per Title 21 of the Code of Federal Regulations, § 888.3030 Single/multiple component metallic bone fixation appliances and accessories. The device Product Code is HTN.

7. Information Relating to Performance Standards and Special Controls

The Synthes Metallic Spiked Washers will be manufactured from either implant quality 316L stainless steel meeting ASTM F138 or CP Titanium meeting ASTM F67. Synthes is not aware of any performance standards or special controls established to this date.

8. Sterilization Information

Synthes will provide the device either sterile or non-sterile. Sterilization information for the sterile device can be found in Attachment I(a). Non-sterile devices must be sterilized prior to use; moist heat sterilization is recommended using the parameters identified in Attachment I(b). These parameters have been validated to assure a Sterility Assurance Level (SAL) of 10^{-6}. This device is intended for single use only.

9. Description of the Device

The Synthes Spiked Washers are available in either implant quality 316L stainless steel or CP titanium. The washer for use with 2.7 mm screws has an inner diameter of 3.2 mm and an outer diameter of 8.0 mm. The washer for use with 3.5 mm and 4.0 mm screws has an inner diameter of 4.0 mm and an outer diameter of 13.5 mm. The washer for use with 4.5 mm and 6.5 mm screws has an inner diameter of 5.5 mm and an outer diameter of 13.5 mm. The smaller washer with the 8.0 mm outer diameter has six spikes while the two larger washers with an outer diameter of 13.5 mm both have eight spikes.

Confidential engineering drawings of the Synthes Metallic Spiked Washers can be found in Attachment II.

10. Proposed Labels and Labeling

Proposed labels and labeling for this device can be found in Attachment III.

11. Commercially Available Device Information

The predicate devices for the Synthes Metallic Spiked Washer are the Synthes Spiked Washer and the Synthes Titanium Locked Spiked Washer which were cleared via 510(k) premarket notifications #K914472 and #K924455 respectively. All these devices have the same indications, are made of the same material(s), have similar features, and are available in a similar range of sizes. Information on the predicate devices can be found in Attachment IV.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 8 2002

Mr. Matthew M. Hull, RAC
Senior Regulatory Associate
Synthes
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K013806
Trade Name: Synthes Metallic Spiked Washers
Regulation Number: 888.3030
Regulation Name: Washer, bolt, nut, non-spinal
Regulatory Class: II
Product Code: HTN
Dated: November 9, 2001
Received: November 15, 2001

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013806

2. Indications for Use Statement

510(k) Number (if known): _____

Device Name: Synthes Metallic Spiked Washers

Indications for Use: The Metallic spiked washers are indicated for ligament reattachment or fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013806